Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

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Report Date:04/29/2009

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				M	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058810504 052000706 059902304 059902006 058814807	05/09/02 08/24/04 04/11/02 04/15/03 02/04/03	728 730 728 730 728	50 (1) 50 (1) 50 (1) 50 (1) 50 (1)	39(688) 34(689) 34(692) 38(691) 35(702)	56.7 56.4 56.2 56.6 52.7	Isoeugenol Kava kava extract beta-Myrcene Pulegone 3,3',4,4'-Tetrachloroazobenzene
				Fer	nale		
Battelle Columbus Laboratory	058810504 052000706 059902304 059902006 058814807	05/08/02 08/23/04 04/10/02 04/14/03 02/03/03	727 729 727 729 731	49 (5) 50 (5) 50 (5) 49 (5) 50 (5)	34(679) 38(695) 39(705) 35(705) 35(675)	65.0 66.2 64.1 64.9 63.2	Isoeugenol Kava kava extract beta-Myrcene Pulegone 3,3',4,4'-Tetrachloroazobenzene

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 5

			Male				Female	
All Organs: Benign Tumors								
		33/50 (66%) 30/50 (60%)	34/50 (68%) 30/50 (60%)	33/50 (66%)		20/49 (41%) 27/49 (55%)	26/50 (52%) 24/50 (48%)	21/50 (42%)
verall Incidence	Total	160/250 (64%)	Mean 64%	SD 3.74%	Total	118/248 (47.58%)	Mean 47.58%	SD 6.19%
All Organs: Malignant Tumors								
		20/50 (40%) 19/50 (38%)	32/50 (64%) 28/50 (56%)	30/50 (60%)		21/49 (43%) 20/49 (41%)	19/50 (38%) 13/50 (26%)	14/50 (28%)
Overall Incidence	Total	129/250 (51.6%)	Mean 51.6%	SD 11.87%	Total	87/248 (35.08%)	Mean 35.13%	SD 7.66%
#All Organs: Malignant and Benign T	umors	43/50 (86%)	47/50 (94%)	43/50 (86%)		34/49 (69%)	39/50 (78%)	30/50 (60%)
Overall Incidence	Total	38/50 (76%) 212/250 (84.8%)	41/50 (82%) Mean 84.8%	SD 6.57%	Total	40/49 (82%) 172/248 (69.35%)	29/50 (58%) Mean 69.4%	SD 10.51%
All Organs: Hemangioma			•••••					
3		0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 1/50 (2%)	2/50 (4%)
overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	4/248 (1.61%)	Mean 1.61%	SD 1.68%
All Organs: Hemangiosarcoma	•••••							
		3/50 (6%) 3/50 (6%)	6/50 (12%) 3/50 (6%)	7/50 (14%)		1/49 (2%) 3/49 (6%)	1/50 (2%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	22/250 (8.8%)	Mean 8.8%	SD 3.9%	Total	6/248 (2.42%)	Mean 2.43%	SD 2.24%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Hemangiosarcoma or Her	mangioma	2/50 (69/)	8/50 (16%)	7/50 /4/9/\		1/40 (20/)	1/50 (20/)	2/50 (69/)
		3/50 (6%) 3/50 (6%)	8/50 (16%) 3/50 (6%)	7/50 (14%)		1/49 (2%) 4/49 (8%)	1/50 (2%) 1/50 (2%)	3/50 (6%)
Overall Incidence	Total	24/250 (9.6%)	Mean 9.6%	SD 4.98%	Total	10/248 (4.03%)	Mean 4.04%	SD 2.88%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 3/49 (6%)	3/50 (6%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	7/248 (2.82%)	Mean 2.82%	SD 3.07%
Overall Incidence	Total	0/50 (0%) 1/50 (2%) 5/250 (2%)	2/50 (4%) 1/50 (2%) Mean 2%	1/50 (2%) SD 1.41%	Total	11/49 (22%) 6/49 (12%) 32/248 (12.9%)	6/50 (12%) 2/50 (4%) Mean 12.94%	7/50 (14%) SD 6.57%
#All Organs:								
Mesothelioma: Benign, M	alignant, NO		- / / /				- ()	- ()
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant						•••••		
_		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories
Species: MICE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
All Organs: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%
All Organs: Osteosarcoma					•••••			
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
All Organs: Osteosarcoma or Osteom	 na							
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
drenal Cortex: Adenoma								
		3/50 (6%)	0/50 (0%)	2/50 (4%)		0/48 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	1/50 (2%) 9/250 (3.6%)	3/50 (6%) Mean 3.6%	SD 2.61%	Total	1/49 (2%) 2/246 (0.81%)	0/49 (0%) Mean 0.81%	SD 1.11%
drenal Cortex: Plasma Cell Tumor Malig	nant							
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/246 (0%)	0/49 (0%) Mean 0%	SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: CORN OIL

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

				Ma	ale						Fem	ale		
*Adrenal Cortex: Sarcoma		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/48	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0,00	(0,0)		0/49	(- · - /	0/49	(0%)	0,00	(070)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD	0%	Total	0/246	(0%)	Mea	n `0%´	SD	0%
Adrenal Medulla: Pheochromocytoma Benign								•••••						
		0/50 1/50	(0%) (2%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/48 1/49	` ,	0/50 0/49	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	1/250	` '		0.4%	SD	0.89%	Total		(0.41%)		n 0.41%	SD	0.91%
Adrenal Medulla: Pheochromocytoma Complex		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/48	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/50 0/250	(0%) (0%)	0/50 Mean	(0%) 0%	SD	0%	Total	0/49 0/246	()	0/49 Mea	(0%) n 0%	SD	0%
Adrenal Medulla: Pheochromocytoma Malignar								•••••						
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/48 0/49	(0%) (0%)	0/50 1/49	(0%) (2%)	0/50	(0%)
Overall Incidence	Total	0/250	` ,	Mean			0%	Total		(0.41%)		n 0.41%		0.91%
Adrenal Medulla: Pheochromocytoma: Benign,									• • • • • • • • • • • • • • • • • • • •					
	CCpiox	0/50 1/50	(0%) (2%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/48 1/49	(- · - /	0/50 1/49	(0%) (2%)	0/50	(0%)
Overall Incidence	Total	1/250	` '		0.4%	eD.	0.89%	Total		(0.81%)		n 0.82%	SD.	1.12%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Female Male *Bone Marrow: Hemangioma 0/50 (0%)1/50 (0%)0/48 (0%)0/50 (0%)(0%)(0%)(0%)(0%)(0%)0/50 0/50 0/49 0/50 1/250 (0.4%) **Overall Incidence** Total Mean 0.4% SD 0.89% Total 0/247 (0%) Mean 0% SD 0% *Bone Marrow: Hemangiosarcoma 0/50 (0%)2/50 (4%)0/48 (0%)0/50 (0%)(0%)0/50 (0%)(0%)1/49 (2%)0/50 (0%)**Overall Incidence** Total 2/250 (0.8%) Mean 0.8% SD 1.79% Total SD 0.91% 1/247 (0.4%) Mean 0.41% *Bone Marrow: **Plasma Cell Tumor Malignant** 0/50 (0%)0/50 (0%)(0%)0/48 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/250 (0%) Mean 0% SD 0% Total 0/247 (0%) Mean 0% #Bone: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/490/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** 0/250 (0%) SD 0% Mean 0% SD 0% Total Mean 0% Total 0/248 (0%)

0/50

SD 0%

0/49

0/49

0/248

Total

(0%)

(0%)

(0%)

(0%)

Mean 0%

0/50

0/50

Total

0/50

0/50

0/250

(0%)

(0%)

(0%)

#Bone: Osteoma

Overall Incidence

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0/50

0/50

(0%)

(0%)

Mean 0%

0/50

SD 0%

(0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Bone: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
#Bone: Osteosarcoma or Osteoma	1							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
#Bone: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Benign								
moningionia Borngii		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Malignant							•••••	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	1/50 (2%) Mean 0.4%	SD 0.89%	Total	0/49 (0%) 0/247 (0%)	0/49 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories Species: MICE

Species: MICE **Strain:** B6C3F1

Length of Study: CHRONIC

				M	ale						Fema	ıle		
Brain: Meningioma: Benign, Malig	nant, NOS	0/50	(00()	0/50	(00/)	0/50	(00()		0/40	(00()	0/50	(00()	0/50	(00()
		0/50 0/50	(0%) (0%)	0/50 1/50	(0%) (2%)	0/50	(0%)		0/49 0/49	(0%) (0%)	0/50 0/49	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	1/250 (0	` '		0.4%	SD	0.89%	Total		(0%)	Mear	` '	SD	0%
Brain: Schwannoma Malignant								•••••						
•		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/49 0/49	(0%) (0%)	0/50 0/49	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	0/250 (0	0%)	Mear	0%	SD	0%	Total	0/247	(0%)	Mear	0%	SD	0%
Clitoral/Preputial Gland: Adenoma	•••••			•••••									•••••	
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/47 0/47	(0%) (0%)	0/49 0/49	(0%) (0%)	0/49	(0%)
Overall Incidence	Total	0/250 (0	0%)	Mear	0%	SD	0%	Total	0/241	(0%)	Mear	` '	SD	0%
Clitoral/Preputial Gland: Carcinoma	•••••	•••••		•••••	•••••		•••••						•••••	
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/47 0/47	(0%) (0%)	0/49 1/49	(0%) (2%)	0/49	(0%)
overall Incidence	Total		0%)	Mear	` '	SD	0%	Total	1/241	(0.41%)	Mear	0.41%	SD	0.91%
Clitoral/Preputial Gland: Carcinoma or Adenoma														
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/47 0/47	(0%) (0%)	0/49 1/49	(0%) (2%)	0/49	(0%)
Overall Incidence	Total	0/250 (0	` '	Mear	` '	SD	0%	Total	1/241	(0.41%)	Mear	0.41%	SD	0.91%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Vehicle: CORN OIL

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Clitoral/Preputial Gland: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/241 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/241 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Carcinoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%) (0/50 (0%)	0/50 (0%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/241 (0%)	Mean 0%	SD 0%
#Esophagus:							•••••	
Squamous Cell Carcinoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Eye: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) (0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 13

			Male				Female	
Harderian Gland: Adenoma								
		8/50 (16%) 6/50 (12%)	5/50 (10%) 9 6/50 (12%))/50 (18%)		3/49 (6%) 7/49 (14%)	5/50 (10%) 14/50 (28%)	4/50 (8%)
verall Incidence	Total	34/250 (13.6%)	Mean 13.6%	SD 3.29%	Total	33/248 (13.31%)	Mean 13.28%	SD 8.77%
Harderian Gland: Carcinoma			•••••					•••••
		4/50 (8%) 1/50 (2%)	0/50 (0%) 1 0/50 (0%)	/50 (2%)		1/49 (2%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/250 (2.4%)	Mean 2.4%	SD 3.29%	Total	2/248 (0.81%)	Mean 0.82%	SD 1.12%
Harderian Gland: Carcinoma or Adenoma					•••••			
		12/50 (24%) 7/50 (14%)	5/50 (10%) 9 6/50 (12%))/50 (18%)		4/49 (8%) 8/49 (16%)	5/50 (10%) 14/50 (28%)	4/50 (8%)
verall Incidence	Total	39/250 (15.6%)	Mean 15.6%	SD 5.55%	Total	35/248 (14.11%)	Mean 14.1%	SD 8.48%
Harderian Gland: Sarcoma								•••••
Garooma		0/50 (0%)	())/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
Heart: Hemangioma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0 0/50 (0%))/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Vehicle: CORN OIL

for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Heart: Hemangiosarcoma 0/50 (0%)0/50 (0%)(0%)0/49 (0%)0/50 (0%)(0%)(0%)(0%)(0%)(0%)0/50 0/50 0/49 0/49 0/247 (0%) **Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total Mean 0% SD 0% *Heart: Sarcoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)(0%)0/50 (0%)(0%)0/49 (0%)0/49 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/247 (0%) Mean 0% SD 0% #Intestine Large: Cecum: Carcinoma 0/50 (0%)0/50 (0%)(0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/250 (0%) Mean 0% SD 0% Total 0/248 (0%) Mean 0% #Intestine Large: Cecum: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)(0%)0/490/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** 0/250 (0%) SD 0% Mean 0% SD 0% Total Mean 0% Total 0/248 (0%) #Intestine Large: Cecum: Leiomyoma (0%)0/50 (0%)0/50 0/50 0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%)Mean 0% SD 0% Total 0/248 (0%) Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Groups R

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female	
#Intestine Large: Colon/Rectun	n:					
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)	,
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0	0% Total	0/248 (0%) Mean 0%	% SD 0%
#Intestine Small: Duodenum: Adenoma						
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 1/50 (2% 0/49 (0%) 0/50 (0%	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0	0.89% Total	1/248 (0.4%) Mean 0.4	\$\ SD 0.89\%
#Intestine Small: Duodenum: Carcinoma	•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0	0% Total	0/248 (0%) Mean 0%	•
#Intestine Small: Duodenum: Leiomyosarcoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0	% Total	0/248 (0%) Mean 0%	•
#Intestine Small: Duodenum: Polyp Adenomatous						
••		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0	0% Total	0/248 (0%) 0/30 (07) Mean 0%	,

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories Species: MICE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

			Male				Female	
Intestine Small: Ileum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
ntestine Small: Ileum: Hemangiosarcoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
Intestine Small: Ileum: Polyp Adenomatous	•••••				• • • • • • • • • • • • • • • • • • • •			
,,		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/30 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
ntestine Small: Jejunum: Adenoma					•••••			
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/49 (0%) 1/248 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%
Intestine Small: Jejunum: Carcinoma	•••••		•••••		•••••	•••••		
		0/50 (0%) 0/50 (0%)	1/50 (2%) 2/50 (4%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/250 (1.2%)	2/50 (4%) Mean 1.2%	SD 1.79%	Total	1/248 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE
Vehicle: CORN OIL

			Male				Female	
Intestine Small: Jejunum: Hemangiosarcoma								
-		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/5 0/50 (0%)	60 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)		SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5 0/50 (0%)	60 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Polyp Adenomatous	•••••							
••		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5 0/50 (0%)	60 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspeci Adenoma					•••••			
		0/50 (0%) 0/50 (0%)	2/50 (4%) 0/5 0/50 (0%)	60 (0%)		0/49 (0%) 0/49 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/250 (0.8%)		SD 1.79%	Total	2/248 (0.81%)	Mean 0.8%	SD 1.79%
Intestine Small: Site Unspeci Carcinoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/5 2/50 (4%)	60 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/250 (1.2%)	` '	SD 1.79%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 18

			Male				Female				
#Intestine Small: Site Unspecified: Carcinoma or Adenoma											
Carcinoma or Adenom	a	0/50 (0%) 0/50 (0%)	3/50 (6%) 2/50 (4%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	2/50 (4%) 0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.83%	Total	3/248 (1.21%)	Mean 1.2%	SD 1.79%			
Intestine Small: Site Unsp Hemangiosarcoma											
-		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/248 (0%)	Mean 0%	SD 0%			
Intestine Small: Site Unsp Leiomyosarcoma											
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%			
Intestine Small: Site Unsp Polyp Adenomatous											
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%			
Islets, Pancreatic: Adenoma											
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	1/50 (2%) 1/49 (2%)	0/50 (0%)			
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/245 (0.82%)	Mean 0.81%	SD 1.11%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories Species: MICE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

			Male				Female	
Islets, Pancreatic: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 1/49 (2%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/49 (0%) 1/245 (0.41%)	1/49 (2%) Mean 0.41%	SD 0.91%
slets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	1/50 (2%) 2/49 (4%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	3/245 (1.22%)	Mean 1.22%	SD 1.82%
Kidney: Renal Tubule: Adenoma								
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 3/250 (1.2%)	0/50 (0%) Mean 1.2%	SD 1.1%	Total	1/49 (2%) 1/245 (0.41%)	0/49 (0%) Mean 0.41%	SD 0.91%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/245 (0%)	0/49 (0%) Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma					••••			
		1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%)		0/47 (0%) 1/49 (2%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	3/250 (1.2%)	0/30 (0%) Mean 1.2%	SD 1.1%	Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 20

			Male				Female	
Kidney: Renal Tubule: Hemangioma								
-		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/245 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/245 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Plasma Cell Tumor Maligi	nant							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
Liver: Cholangiocarcinoma							•••••	
onorangio caronicana		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/247 (0%)	0/49 (0%) Mean 0%	SD 0%
Liver: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	(****)		0/49 (0%)	0/49 (0%)	,
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Liver: Hemangioma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma	•••••	4/50 (00/)	5/50 (400/)	5/50 /400/)		0/40 (00/)	4/50 (004)	0/70 (004)
Overall Incidence	Total	1/50 (2%) 0/50 (0%) 12/250 (4.8%)	5/50 (10%) 1/50 (2%) Mean 4.8%	5/50 (10%) SD 4.82%	Total	0/49 (0%) 0/49 (0%) 1/247 (0.4%)	1/50 (2%) 0/49 (0%) Mean 0.4%	0/50 (0%) SD 0.89%
	10tai	12/250 (4.6%)	ivieaii 4.076			1/247 (0.4%)		
*Liver: Hepatoblastoma								
		3/50 (6%) 1/50 (2%)	0/50 (0%) 2/50 (4%)	4/50 (8%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	10/250 (4%)	Mean 4%	SD 3.16%	Total	0/247 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma								
		24/50 (48%) 22/50 (44%)	27/50 (54%) 22/50 (44%)	26/50 (52%)		11/49 (22%) 13/49 (27%)	8/50 (16%) 3/49 (6%)	6/50 (12%)
Overall Incidence	Total	121/250 (48.4%)	Mean 48.4%	SD 4.56%	Total	41/247 (16.6%)	Mean 16.62%	SD 8.13%
*Liver: Hepatocellular Carcinoma								
		8/50 (16%) 13/50 (26%)	17/50 (34%)	14/50 (28%)		3/49 (6%) 5/49 (10%)	3/50 (6%) 2/49 (4%)	1/50 (2%)
Overall Incidence	Total	72/250 (28.8%)	Mean 28.8%	SD 9.01%	Total	14/247 (5.67%)	Mean 5.68%	SD 3.04%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

.. May 2000

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 22

				M	ale					Fema	ile		
Liver:	Hanatah												
Hepatocellular Carcinoma or	нератор	11/50	(22%)	20/50	(40%)	16/50 (32%)		3/49	(6%)	3/50	(6%)	1/50	(2%)
		13/50	(26%)	19/50	(38%)	,		5/49	(10%)	2/49	(4%)		,
overall Incidence	Total		(31.6%)		31.6%	SD 7.67%	Total	14/247	(5.67%)		5.68%		3.04%
iver:		· • • • • • • • • • • • • • • • • • • •		•••••			• • • • • • • • • • • • • • • • • • • •						
Hepatocellular Carcinoma or	Hepatoc			_									
		28/50 29/50	` '	38/50 34/50	(76%) (68%)	33/50 (66%)		13/49 17/49	` '	10/50 4/49	(20%) (8%)	7/50	(14%)
Overall Incidence	Total	29/50 162/250	(58%) (64.8%)		(66%)	SD 8.07%	Total	51/247	` ,		(8%) 1 20.68%	8D	10.4%
verali ilicidence			, ,						,				
Hepatocellular Carcinoma, H Hepatoblastoma verall Incidence	Total	30/50 29/50 165/250	(60%) (58%)	38/50 34/50 Mear	(76%) (68%) 66%	34/50 (68%) SD 7.21%	Total	13/49 17/49 51/247	(35%)	10/50 4/49 Mean	(20%) (8%) 20.68%	7/50 SD	(14%) 10.4%
∟iver: Hepatocholangiocarcinoma													
riopatoonolangiooai onionia		2/50	(4%)	4/50	(8%)	0/50 (0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)			0/49	(0%)	0/49	(0%)		
		0/50	(0%)	1/00	(/							SD	00/
verall Incidence	Total	7/250 (, ,		2.8%	SD 3.35%	Total	0/247	(0%)	Mean	0%	30	0%
		7/250 ((2.8%)	Mear	2.8%				` '				
_iver:		7/250 ((2.8%)	Mear	2.8%				` '				
		7/250 ((2.8%)	Mear	2.8%				` '				
Overall Incidence Liver: Hepatocholangioma		7/250 ((2.8%)	Mear	2.8%								

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Vehicle: CORN OIL

Route: GAVAGE

Report Date:04/29/2009

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Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

			Male	Female
*Liver: Ito Cell Tumor Benign		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/247 (0%) Mean 0% SD 0%
*Liver: Ito Cell Tumor Malignan	ıt	0/50 (0%)	0/50 (0%) 2/50 (4%)	0/49 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 2/30 (4/8)	0/49 (0%) 0/49 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8% SD 1.79%	Total 0/247 (0%) Mean 0% SD 0%
*Liver: Plasma Cell Tumor Mali		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/247 (0%) Mean 0% SD 0%
*Liver: Sarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 1/50 (2%) 0/50 (0%) 0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 1/247 (0.4%) Mean 0.4% SD 0.89%
*Lung: Adenoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/48 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/246 (0%) Mean 0% SD 0%

^{......} *: Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

			Male		Female	
*Lung: Alveolar/Bronchiolar Ad	denoma	6/50 (12%)	9/50 (18%) 8/50	(16%)	4/48 (8%) 2/50 (4%)	4/50 (8%)
Overall Incidence	Total	6/50 (12%) 34/250 (13.6%)	5/50 (10%) Mean 13.6% SD :	3.29% Total	1/49 (2%) 3/49 (6%) 14/246 (5.69%) Mean 5.7%	SD 2.68%
*Lung: Alveolar/Bronchiolar Ca	arcinoma					
Alveola/Bronomolar of	arcinoma	2/50 (4%) 3/50 (6%)	2/50 (4%) 5/50 3/50 (6%)	(10%)	0/48 (0%) 2/50 (4%) 2/49 (4%) 0/49 (0%)	2/50 (4%)
Overall Incidence	Total	15/250 (6%)	Mean 6% SD :	2.45% Total	6/246 (2.44%) Mean 2.42%	SD 2.21%
*Lung: Alveolar/Bronchiolar Ca Adenoma	arcinoma or Alv		44/E0 (220/) 42/E0	(269/)	4/49 (99/) 4/EO (99/)	S/EO (429/)
Overall Incidence	Total	7/50 (14%) 9/50 (18%) 47/250 (18.8%)	11/50 (22%) 13/50 7/50 (14%) Mean 18.8% SD :	(26%) 5.22% Total	4/48 (8%) 4/50 (8%) 3/49 (6%) 3/49 (6%) 20/246 (8.13%) Mean 8.12%	6/50 (12%) SD 2.4%
*Lung: Fibrosarcoma		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/48 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0% SD	0% Total	0/49 (0%) 0/49 (0%) 0/246 (0%) Mean 0%	SD 0%
*Lung: Fibrous Histiocytoma		0/50 (00()	0/50 /00/\	(00()	0/40 (00) 0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 0/50 (0%) Mean 0% SD	(0%) 0% Total	0/48 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%) 0/246 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Lung: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Lung: Plasma Cell Tumor Malig	nant							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
#Lymph Node: Fibrous Histiocytoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 26 Report Date: 04/29/2009

Species: MICE Strain: B6C3F1 Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male		Female
#Lymph Node: Hemangiosarcoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/248 (0%)	Mean 0% SD 0%
#Lymph Node: Plasma Cell Tumor Malign	ant				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	,	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/248 (0%)	Mean 0% SD 0%
#Lymph Node: Sarcoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	,	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/248 (0%)	Mean 0% SD 0%
#Lymph Node, Bronchial: Hemangiosarcoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	,	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/248 (0%)	Mean 0% SD 0%
#Lymph Node, Mandibular: Fibrous Histiocytoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/248 (0%)	Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 27

			Male				Female	
Lymph Node, Mandibular: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Mast Cell Tumor Malignant	•••••					•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Plasma Cell Tumor Maligna	nt							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Fibrous Histiocytoma						•••••		
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

telected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Lymph Node, Mesenteric: Hemangiosarcoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Malig	nant							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoacanthoma					••••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
#Mammary Gland: Adenoma					•••••			
Additiona		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

III. May2009

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 29

			Male				Female	
#Mammary Gland: Carcinoma or Adenoma	l							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
#Mammary Gland: Fibroadenoma						•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma	ı or Adenoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenoma						•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
Mesentery: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 30

			Male				Female	
Mesentery: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
Mesentery: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Mesentery: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Nose:								
Mast Cell Tumor Maligna	ant	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, 7 Papilloma Squamous or	Гongue, Phary		•••••	•••••		•••••		•••••
•	•	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

				М	ale						Fema	ale		
Oral Cavity (Oral Mucosa, Squamous Cell Carcino		nx, Tooth,	Gingiva):											
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	1/50	(2%)		0/49 0/49	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
verall Incidence	Total	1/250			0.4%	SD	0.89%	Total		(0%)	Mear	` '	SD	0%
									• • • • • • • • • • • • • • • • • • • •		• • • • • • • • • • • • • • • • • • • •		• • • • • • • • • • • • • • • • • • • •	
Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma														
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	1/50	(2%)		0/49 0/49	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
verall Incidence	Total	1/250	` '		0.4%	SD	0.89%	Total	0/248	, ,	Mear		SD	0%
													• • • • • • • • • • • • • • • • • • • •	
Ovary: Choriocarcinoma									0/40	(00/)	0/40	(00/)	0/50	(00/)
									0/48 0/49	(0%) (0%)	0/49 0/49	(0%) (0%)	0/50	(0%)
verall Incidence								Total	0/245	(0%)	Mear	n 0%	SD	0%
													• • • • • • • • • • • • • • • • • • • •	
Ovary: Cystadenoma														
									3/48 1/49	(6%) (2%)	5/49 2/49	(10%) (4%)	2/50	(4%)
verall Incidence								Total		(5.31%)		5.32%	SD	3.11%
Ovary: Fibrous Histiocytoma														
-									0/48 0/49	(0%) (0%)	0/49 0/49	(0%) (0%)	0/50	(0%)
									0/49	(0 /0)	0/43	(0/0)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

	Male		Female
*Ovary: Granulosa Cell Tumor Benign			
Granulosa Celi Tumor Benign			0/49 (0%) 0/50 (0%)
Overall Incidence	Total	1/49 (2%) 1/245 (0.41%)	0/49 (0%) Mean 0.41% SD 0.91%
		,	
*Ovary:			
Granulosa Cell Tumor Malignant		0/48 (0%)	0/49 (0%) 0/50 (0%)
Overall Incidence	Tatal	` '	0/49 (0%)
Overall Incidence	Total	0/245 (0%)	Mean 0% SD 0%
*Ovary:			
Granulosa Cell Tumor: Benign, Malignant, NOS		0/48 (0%)	0/49 (0%) 0/50 (0%)
		1/49 (2%)	0/49 (0%)
Overall Incidence	Total	1/245 (0.41%)	Mean 0.41% SD 0.91%
*Ovary:			
Hemangioma		0/49 (00/)	0/49 (0%) 0/50 (0%)
		0/48 (0%) 1/49 (2%)	0/49 (0%) 0/50 (0%) 1/49 (2%)
Overall Incidence	Total	2/245 (0.82%)	Mean 0.82% SD 1.12%
*Outen::			
*Ovary: Hemangiosarcoma			
			0/49 (0%) 0/50 (0%) 0/49 (0%)
Overall Incidence	Total	1/245 (0.41%)	Mean 0.41% SD 0.91%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Page: 33 Report Date: 04/29/2009

Species: MICE Strain: B6C3F1

Vehicle: CORN OIL

Length of Study: CHRONIC

	Male			Female	
*Ovary: Leiomyosarcoma					
• • • • • • • • • • • • • • • • • • • •			0/48 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence		Total	0/49 (0%) 0/245 (0%)	0/49 (0%) Mean 0%	SD 0%
*Ovary:		•••••			
Luteoma			0/48 (0%) 0/49 (0%)	1/49 (2%) 0/49 (0%)	1/50 (2%)
Overall Incidence		Total	2/245 (0.82%)	Mean 0.81%	SD 1.11%
*Ovary:					
Plasma Cell Tumor Malignant			0/48 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence		Total	0/49 (0%) 0/245 (0%)	0/49 (0%) Mean 0%	SD 0%
*Ovary:					
Teratoma Benign			0/48 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence		Total	0/49 (0%) 1/245 (0.41%)	1/49 (2%) Mean 0.41%	SD 0.91%
*Ovary: Teratoma Malignant			0/40 (00/)	0/40 (00/)	0(50 (00))
			0/48 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence		Total	0/245 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories
Species: MICE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Ovary: Tubulostromal Adenoma								
						0/48 (0%)	0/49 (0%)	0/50 (0%)
verall Incidence					Total	0/49 (0%) 0/245 (0%)	0/49 (0%) Mean 0%	SD 0%
veran meldence					Total	0/243 (0/0)	Wicaii 070	OD 070
Pancreas: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
		` ,				, ,		
Pancreas: Carcinoma								•••••
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/49 (0%)	05.00/
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/244 (0%)	Mean 0%	SD 0%
ancreas: Carcinoma or Adenoma	• • • • • • • • • • • • • • • • • • • •							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/49 (0%)	0/50 (0%)
venell le siden se	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/49 (0%)	0/49 (0%)	CD 00/
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/244 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distalis o Adenoma								
		0/50 (0%)	0/49 (0%)	0/49 (0%)		4/47 (9%)	2/50 (4%)	1/50 (2%)
	T-1-1	0/50 (0%)	0/49 (0%)	00.00/	T-1-1	2/49 (4%)	1/49 (2%)	00.0000
verall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	10/245 (4.08%)	Mean 4.13%	SD 2.65%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

Page: 35 Tumor Incidence for Selected Control Animal Groups Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
Pituitary Gland: Pars Dist Carcinoma	talis or Unspecif	fied Site:						
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Dist Carcinoma or Adenom	talis or Unspecif			•••••				
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)		4/47 (9%) 2/49 (4%)	2/50 (4%) 1/49 (2%)	1/50 (2%)
verall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	10/245 (4.08%)	Mean 4.13%	SD 2.65%
Pituitary Gland: Pars Inte Adenoma	ermedia:							
		0/50 (0%) 0/50 (0%)	1/49 (2%) 0/49 (0%)	0/49 (0%)		0/47 (0%) 0/49 (0%)	1/50 (2%) 0/49 (0%)	0/50 (0%)
verall Incidence	Total	1/247 (0.4%)	Mean 0.41%	SD 0.91%	Total	1/245 (0.41%)	Mean 0.4%	SD 0.89%
Pituitary Gland: Pars Inte Carcinoma or Adenom	ermedia:							
		0/50 (0%) 0/50 (0%)	1/49 (2%) 0/49 (0%)	0/49 (0%)		0/47 (0%) 0/49 (0%)	1/50 (2%) 0/49 (0%)	0/50 (0%)
verall Incidence	Total	1/247 (0.4%)	Mean 0.41%	SD 0.91%	Total	1/245 (0.41%)	Mean 0.4%	SD 0.89%
Prostate: Adenoma	•••••				•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 36 Report Date:04/29/2009

Species: MICE

Contract/Lab: All Laboratories

Strain: B6C3F1

Length of Study: CHRONIC

			Male				Female	
Prostate: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)				
overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%				
Prostate: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%				
Salivary Glands: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
Salivary Glands: Carcinoma or Adenoma						•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
Salivary Glands: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

. May2000

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 37

			Male				Female	
Seminal Vesicle: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%				
Skeletal Muscle: Fibrosarcoma			•••••				•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Myxosarcoma			•••••					
myxosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	3/50 (6%) 2/50 (4%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	5/248 (2.02%)	Mean 2%	SD 2.83%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

#Skeletal Muscle: Rhabdomyosarcoma or Rhabdomyosar Rhabdomyosarcoma or Total 1/250 (0/%) 0/50 (0				Male				Female	
Overall Incidence Total 1/250 (0.4%) Mean 0.4% SD 0.89% Total 5/248 (2.02%) Mean 2% SD 2.83% #Skeletal Muscle: Sarcoma Sarcoma 0/50 (0%) 0/50 (or Rhabdomyom	0/50 (0%)		0/50 (0%)		()		0/50 (0%)
#Skeletal Muscle: Sarcoma 0/50 (0%) 0/50 (0	Overall Incidence	Total	` '	` '	SD 0.80%	Total	(/	` '	SD 2 839/
#Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma 0/50 (0%) 0/50 (` ,				,	ivieaii 270	3D 2.03 //
Overall Incidence Total 0/250 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/248 (0%) 0/50 (0%) Mean 0% SD 0% **Skin: **Basal Cell Adenoma or Basosquamous Tumor Benign 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) **Skin: **Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma **Overall Incidence Total 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) **Skin: **Basal Cell Carcinoma** **Skin: **Basal Cell Carcinoma** **Skin: **Basal Cell Carcinoma** **Skin: **Basal Cell Carcinoma** **Overall Carcinoma** **Over	#Skeletal Muscle:								
Overall Incidence Total 0/250 (0%) Mean 0% SD 0% Total 0/248 (0%) Mean 0% SD 0% #Skin:				` ,	0/50 (0%)		()		0/50 (0%)
#Skin: Basal Cell Adenoma or Basosquamous Tumor Benign 0/50 (0%) 0/50 (0%	Overall Incidence	Total	` '	` '	SD 0%	Total	()	` ,	SD 0%
Basal Cell Adenoma or Basosquamous Tumor Benign									
#Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma #Skin: Basal Cell Adenoma Total 0/250 (0%) 0/50 (0%)	=	r Basosquamou	s Tumor Benign						
Overall Incidence Total 0/250 (0%) Mean 0% SD 0% Total 1/248 (0.4%) Mean 0.4% SD 0.89% #Skin:					0/50 (0%)		()		1/50 (2%)
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma	Overall Incidence	Total	` '	` '	SD 0%	Total	(,	(/	SD 0.89%
#Skin: Basal Cell Carcinoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)	Basal Cell Adenoma, E	Basosquamous ∃	Fumor Benign, or						
#Skin: Basal Cell Carcinoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	тиспосриненота			` ,	0/50 (0%)		` ,		1/50 (2%)
Basal Cell Carcinoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%)	Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)			(201)	(004)	(201)		2/12 (22)	(004)	2/20 (00)
					0/50 (0%)		()	()	0/50 (0%)
Overall Incidence Total 0/250 (0%) Mean 0% SD 0% Total 0/248 (0%) Mean 0% SD 0%	Overall Incidence	Total	` ,	` '	SD 0%	Total	()	` ,	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Skin: Basal Cell Carcinoma o NOS)	or Basosquamo	us Tumor (malignant	or					
,		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
Skin: Basal Cell Carcinoma, Tumor (benign, maligna			0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Basal or Sq. Cell Carcil or B), Basal Cell Aden	noma, Carcinon oma, Adenoma,	Papilloma, Sq						
Basal or Sq. Cell Carcii or B), Basal Cell Adeno Papilloma, Keratoacant	noma, Carcinon oma, Adenoma,	Papilloma, Sq	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/49 (0%) 2/248 (0.81%)	0/50 (0%) 1/50 (2%) Mean 0.8%	1/50 (2%) SD 1.1%
Basal or Sq. Cell Carcii or B), Basal Cell Adend Papilloma, Keratoacani Overall Incidence Skin:	noma, Carcinon oma, Adenoma, thoma, Trichoe _l	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	(,	Total	0/49 (0%)	1/50 (2%)	(11,
Basal or Sq. Cell Carcir or B), Basal Cell Adeno Papilloma, Keratoacant Overall Incidence	noma, Carcinon oma, Adenoma, thoma, Trichoe _l	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	(,	Total	0/49 (0%) 2/248 (0.81%) 	1/50 (2%) Mean 0.8% 	(11,
Basal or Sq. Cell Carcin or B), Basal Cell Adeno Papilloma, Keratoacant verall Incidence Skin: Basosquamous Tumor	noma, Carcinon oma, Adenoma, thoma, Trichoe _l	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total Total	0/49 (0%) 2/248 (0.81%)	1/50 (2%) Mean 0.8%	SD 1.1%
Basal or Sq. Cell Carcin or B), Basal Cell Adend Papilloma, Keratoacant Overall Incidence Skin: Basosquamous Tumor	noma, Carcinon oma, Adenoma, thoma, Trichoep Total	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	SD 0% 0/50 (0%)		0/49 (0%) 2/248 (0.81%) 0/49 (0%) 0/49 (0%)	1/50 (2%) Mean 0.8% 0/50 (0%) 0/50 (0%)	SD 1.1%
Basal or Sq. Cell Carcin or B), Basal Cell Adend Papilloma, Keratoacant Overall Incidence Skin: Basosquamous Tumor Overall Incidence	noma, Carcinon oma, Adenoma, thoma, Trichoep Total	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	SD 0% 0/50 (0%)		0/49 (0%) 2/248 (0.81%) 0/49 (0%) 0/49 (0%) 1/248 (0.4%)	1/50 (2%) Mean 0.8% 0/50 (0%) 0/50 (0%) Mean 0.4%	SD 1.1%
Basal or Sq. Cell Carcin or B), Basal Cell Adeno Papilloma, Keratoacant Dverall Incidence #Skin: Basosquamous Tumor Dverall Incidence	noma, Carcinon oma, Adenoma, thoma, Trichoep Total	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	SD 0% 0/50 (0%) SD 0%		0/49 (0%) 2/248 (0.81%) 0/49 (0%) 0/49 (0%) 1/248 (0.4%)	1/50 (2%) Mean 0.8% 0/50 (0%) 0/50 (0%) Mean 0.4%	SD 1.1% 1/50 (2%) SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Way2009

Toxicology Data Management SystemTumor Incidence for Selected Control Animal Groups

Page: 40 Report Date:04/29/2009

Contract/Lab: All Laboratories Species: MICE

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skin: Fibroma, Fibrosarcoma, S Fibrous Histiocytoma	Sarcoma, My	koma, Myxosarcoma, o	r					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)		3/49 (6%) 2/49 (4%)	0/50 (0%) 1/50 (2%)	2/50 (4%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	8/248 (3.23%)	Mean 3.24%	SD 2.33%
‡Skin: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 1/50 (2%)	1/50 (2%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	3/248 (1.21%)	Mean 1.21%	SD 1.1%
Histiocytoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 2/250 (0.8%)	0/50 (0%) 1/50 (2%) Mean 0.8%	1/50 (2%) SD 1.1%	Total	3/49 (6%) 2/49 (4%) 8/248 (3.23%)	0/50 (0%) 1/50 (2%) Mean 3.24%	2/50 (4%) SD 2.33%
#Skin: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
Skin: Granular Cell Tumor Beni								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
		0/30 (0/0)	0/30 (0/0)			0/43 (0/0)	0/30 (0/0)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skin: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Hemangiosarcoma								•••••
		1/50 (2%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	1/50 (2%)		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 0.89%	Total	2/248 (0.81%)	Mean 0.81%	SD 1.11%
#Skin: Liposarcoma					•••••			
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Skin:					•••••			
Myxosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Skin:					• • • • • • • • • • • • • • • • • • • •			
Neurofibrosarcoma or S	chwannoma (ı	malignant or NOS) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 2/49 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	3/248 (1.21%)	Mean 1.22%	SD 1.82%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) 0/50 0/50 (0%)0/50 (0%)0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/49 (4%)1/50 (2%)Overall Incidence Total 0/250 (0%) Mean 0% SD 0% Total 3/248 (1.21%) Mean 1.22% SD 1.82% #Skin: Osteosarcoma 0/50 (0%)1/50 (2%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/490/50 (0%)SD 0% Overall Incidence Total 1/250 (0.4%) Mean 0.4% SD 0.89% Total 0/248 (0%) Mean 0% #Skin: Sarcoma 0/50 (0%)0/50 (0%)1/50 3/49 (6%)0/50 (0%)1/50 (2%)(0%) (0%)(0%)0/50 0/49 0/50 (0%)Total 1/250 (0.4%) 4/248 (1.61%) **Overall Incidence** Mean 0.4% SD 0.89% Total Mean 1.62% SD 2.66% #Skin: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/49(0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)2/49 (4%)(2%)0/50 1/50 SD 0% **Overall Incidence** Total 0/250 (0%) Mean 0% Total 3/248 (1.21%) Mean 1.22% SD 1.82% #Skin: **Squamous Cell Carcinoma** 0/50 (0%)0/50 0/50 (0%)0/490/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/248 (0%) Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skin: Squamous Cell Carcino Basosquamous Tumor (
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillon	na							•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Squamous Cell Papillon	na or Papillom	a						
	·	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Squamous Cell Papillon Carcinoma or Keratoaca		Squamous Cell						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Squamous Cell Papillon	na, Papilloma,							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Vehicle: CORN OIL Length of Study: CHRONIC

			Male		Female	•
#Skin: Trichoepithelioma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0%) 0/50 (0%) 0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0		0/248 (0%) Mean	
#Skin: Sebaceous Gland: Adenoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0%) 0/50 (0%) 0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0	% Total	0/248 (0%) Mean	
#Skin: Sebaceous Gland: Carcinoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0%) 0/50 (0%) 0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0		0/248 (0%) Mean	
#Skin: Sebaceous Gland: Carcinoma or Adenoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0%) 0/50 (0%) 0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0	% Total	0/248 (0%) Mean	•
#Spinal Cord: Meningioma Malignant						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0%) 0/50 (0%) 0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0	% Total	0/248 (0%) Mean	,

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Vehicle: CORN OIL

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

			Male	Female
*Spleen: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/48 (0%) 0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/50 (0%) 0/249 (0%)	0/50 (0%) Mean 0% SD 0%	0/49 (0%) 0/49 (0%) Total 0/244 (0%) Mean 0% SD 0%
Jveran mendence		, ,		10tal 0/244 (0/0) Wealt 0/0 05 0/0
Spleen: Hemangioma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%)	0/48 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/244 (0%) Mean 0% SD 0%
Spleen: Hemangiosarcoma				
g		0/50 (0%) 2/50 (4%)	2/50 (4%) 1/49 (2%) 2/50 (4%)	1/48 (2%) 0/49 (0%) 0/49 (0%) 1/49 (2%) 0/49 (0%)
Overall Incidence	Total	7/249 (2.81%)	Mean 2.81% SD 1.78%	Total 2/244 (0.82%) Mean 0.82% SD 1.13%
Spleen: Mast Cell Tumor Malignant				
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%)	0/48 (0%) 1/49 (2%) 0/49 (0%) 0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 1/244 (0.41%) Mean 0.41% SD 0.91%
Spleen: Plasma Cell Tumor Maligna	ınt			
· ·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%)	0/48 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/244 (0%) Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date:04/29/2009

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				Ma	ale						Fema	ıle		
Stomach, Forestomach: Mast Cell Tumor Malignant														
			(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/49 0/49	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
overall Incidence	Total	0/250 (0%	` '	Mean	` '	SD	0%	Total	0/248	` ,	Mear	` ,	SD	0%
Stomach, Forestomach: Squamous Cell Carcinoma				•••••								•••••		
•			(0%) (2%)	1/50 0/50	(2%) (0%)	0/50	(0%)		0/49 0/49	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	2/250 (0.	` '		0.8%	SD	1.1%	Total	0/48	` '	Mear	` '	SD	0%
Stomach, Forestomach: Squamous Cell Carcinoma Overall Incidence	or Papillon Total	0/50	(0%) (2%)	9/50 1/50 Mean	(18%) (2%) 4.4%	0/50 SD	(0%) 7.67%	Total	1/49 2/49 9/248	(2%) (4%) (3.63%)	3/50 2/50 Mear	(6%) (4%) 1 3.62%	1/50 SD	(2%) 1.67%
Stomach, Forestomach: Squamous Cell Papilloma		0/50	(004)	0/50	(400()		(00()			(004)	0/50	(00()	4/50	(00()
			(0%) (0%)	8/50 1/50	(16%) (2%)	0/50	(0%)		1/49 2/49	(2%) (4%)	3/50 2/50	(6%) (4%)	1/50	(2%)
verall Incidence	Total	9/250 (3.	6%)	Mean	3.6%	SD	6.99%	Total	9/248	(3.63%)	Mear	3.62%	SD	1.67%
Stomach, Glandular: Adenoma												•••••	•••••	
			(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		1/49 0/49	(2%) (0%)	1/50 0/50	(2%) (0%)	0/50	(0%)
	Total	0/250 (0%	` '	Mean	` '	SD		Total		(0.81%)		0.81%		1.11%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Route: GAVAGE Vehicle: CORN OIL Page: 47

			Male				Female	
Stomach, Glandular: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/248 (0.81%)	Mean 0.81%	SD 1.11%
Testes: Adenoma	•••••							
		2/50 (4%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 3/250 (1.2%)	0/50 (0%) Mean 1.2%	SD 1.79%				
Testes:								
Hemangiosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%				
Thymus: Thymoma Benign								
		0/48 (0%) 0/49 (0%)	0/48 (0%) 0/41 (0%)	0/47 (0%)		0/47 (0%) 0/48 (0%)	0/50 (0%) 1/48 (2%)	0/49 (0%)
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/242 (0.41%)	Mean 0.42%	SD 0.93%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
Thymus: Thymoma Malignant								
		0/48 (0%) 0/49 (0%)	0/48 (0%) 0/41 (0%)	0/47 (0%)		0/47 (0%) 0/48 (0%)	0/50 (0%) 0/48 (0%)	0/49 (0%)
verall Incidence	Total	0/233 (0%)	Mean 0%	SD 0%	Total	0/242 (0%)	Mean 0%	SD 0%
Гhymus: Thymoma: Benign, Malign								
		0/48 (0%) 0/49 (0%)	0/48 (0%) 0/41 (0%)	0/47 (0%)		0/47 (0%) 0/48 (0%)	0/50 (0%) 1/48 (2%)	0/49 (0%)
Overall Incidence	Total	0/233 (0%)	Mean 0%	SD 0%	Total	1/242 (0.41%)	Mean 0.42%	SD 0.93%
Thyroid Gland: Adenoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/246 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/246 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

ol Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
Thyroid Gland: Follicular Cell: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 1/49 (2%)	0/50 (0%) 0/49 (0%)	1/50 (2%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/246 (0.81%)	Mean 0.81%	SD 1.11%
Thyroid Gland: Follicular Cell: Carcinoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/48 (0%) 1/49 (2%)	0/50 (0%) 2/49 (4%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	3/246 (1.22%)	Mean 1.22%	SD 1.83%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/48 (0%) 2/49 (4%)	0/50 (0%) 2/49 (4%)	1/50 (2%)
overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	5/246 (2.03%)	Mean 2.03%	SD 2.04%
Tissue NOS: Carcinoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
Tissue NOS: Hemangiosarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 50

			Male				Female	
fTissue NOS: Plasma Cell Tumor Maligna	nt							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Tissue NOS: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Tongue: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
tTongue:							•••••	
Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
	-	0/50 (0%)	0/50 (0%)	00.000/	+	0/49 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma o	or Papillon	na Squamous						
-	-	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/49 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

cted Control Animal Groups
GAVAGE

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Tongue: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangioma					•••••			
•		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma								
•		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
*Urinary Bladder:								
Plasma Cell Tumor Malign	ant	0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/245 (0%)	0/49 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: CORN OIL

			Male			Female				
Urinary Bladder: Sarcoma										
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)		
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%		
#Uterus: Adenoma					•••••		•••••			
Adenoma						0/49 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%		
tUterus:	•••••		•••••		• • • • • • • • • • • • • • • • • • • •		•••••			
Carcinoma						0/49 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%		
Uterus:					• • • • • • • • • • • • • • • • • • • •		•••••			
Hemangioma						0/49 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%		
Uterus:										
Hemangiosarcoma						0/49 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/49 (0%)	0/50 (0%)	SD 0%		
Overall Incidence					Total	0/248 (0%)	Mean 0%	SD 0%		

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Species: MICE **Strain:** B6C3F1

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

	Male		Female		
Jterus:					
Leiomyoma			0/49 (0%)	0/50 (0%)	0/50 (0%)
			0/49 (0%)	0/50 (0%)	0/00 (0/0)
verall Incidence		Total	0/248 (0%)	Mean 0%	SD 0%
Jterus:		•••••		•••••	•••••
Leiomyosarcoma					
			0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence		Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
verall incluence			` ,		
Jterus:					
Polyp Stromal			0/40 (00/)	0/50 (40/)	0/50 (00/)
			0/49 (0%) 0/49 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)
verall Incidence		Total	2/248 (0.81%)	Mean 0.8%	SD 1.79%
Jterus:					
Sarcoma Stromal					
			1/49 (2%)	0/50 (0%)	0/50 (0%)
			0/49 (0%)	0/50 (0%)	
verall Incidence		Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
Jterus:					
Sarcoma Stromal or Polyp Stromal					
			1/49 (2%)	2/50 (4%)	0/50 (0%)
verall lasidance		Total	0/49 (0%)	0/50 (0%)	CD 4 700/
verall Incidence		Total	3/248 (1.21%)	Mean 1.21%	SD 1.79%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Mean 0%

SD 0%

Report Date: 04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Schwannoma Malignant 0/49 (0%)0/50 (0%)(0%)(0%)(0%)0/49 0/50 0/248 (0%) **Overall Incidence** Total Mean 0% SD 0% #Vagina: Squamous Cell Carcinoma 0/49 (0%)0/50 (0%)(0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% #Vagina: Squamous Cell Papilloma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/248 (0%) Mean 0% #Zymbal's Gland: Carcinoma 0/50 (0%) (0%) (0%)0/50 (0%)0/49 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** 0/250 (0%) Mean 0% SD 0% Mean 0% SD 0% Total Total 0/248 (0%) #Zymbal's Gland: Carcinoma or Adenoma 0/50 (0%)(0%)0/50 0/50 0/49 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 0/49 (0%)0/50 (0%)

SD 0%

Total

0/248 (0%)

Total

0/250

(0%)

Mean 0%

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied